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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	BSI-010US4	4645
7590 Ratner & Prestia One Westlakes, Berwyn, Suite 301 P.O. Box 980 Valley Forge, PA 19482			EXAMINER MATTHEWS, WILLIAM H	
			ART UNIT 3774	PAPER NUMBER
			MAIL DATE 03/24/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/977,826

**Applicant(s)**

GOICOECHEA ET AL.

**Examiner**

William H. Matthews (Howie)

**Art Unit**

3774

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20, 22-41, 43-49 and 54-62 is/are pending in the application.
- 4a) Of the above claim(s) 26, 34-38, 40 and 58-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20, 22-25, 27-33, 39, 41, 43-49 and 54-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8-27-07
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed 12-26-07 have been fully considered but they are not persuasive.
2. Regarding the rejection under 35 USC 112 of claims 56 and 57, Examiner responds to each of Applicant's arguments below:
  - Regarding the phrase "**abutting apices**", Applicant suggests the passage at page 10, lines 16-23 would lead one of ordinary skill in the art to recognize the specification expressly, implicitly, and inherently supports "abutting apices". Examiner disagrees because the use of "a suture loop" to tie adjacent or juxtaposed apices does not expressly, implicitly, or inherently require contact between the apices. In fact, the teachings at page 10, lines 16-23 raise the question of how tightly or loosely the suture is tied. These teachings are not equivalent to a connection created by adhesive or welding.
  - Regarding the "**non-helical**" limitation in combination with each hoop being substantially perpendicular, Applicant points to page 9, lines 13-19 which references a helical configuration in EP-A-0556850, and a different novel configuration having substantially perpendicular hoops. Applicant suggests this passage describes a "helical" and "non-helical" configuration because the "novel" configuration is described as an alternative to the helical configuration. Examiner disagrees with this analysis because Figure 4A shows the "novel configuration" having substantially perpendicular hoops and a helical aspect

(i.e the longitudinal displacements described at page 23 lines 24-27) . The mere description of an alternative embodiment to a purely helical configuration does not require the alternative embodiment to be "non-helical" (which may be interpreted as lacking **any** helical features).

- Regarding claim 56 and the "**perpendicular**" limitation, Applicant suggests it would be obvious to interchange features of the Figure 1a/2a embodiment and Figure 22/23 embodiments (Remarks page 7, lines 7-10). Examiner disagrees with this analysis because the originally filed specification did not interrelate the embodiments in such a way that Applicant is entitled to combine various features from different embodiments. Furthermore, Examiner notes the "substantially perpendicular" embodiment of figures 1-4a is appropriate because of the longitudinal displacements described at page 23 lines 24-27. This feature is not present in the embodiment of figures 22-23 which is described as perpendicular.
- Regarding the originally filed **abstract**, Applicant notes an objection to the specification was not made under 35 USC 132. Examiner notes that the first action on the merits occurred after the abstract was replaced on 3-1-02 (and correspondingly deleted the issues Examiner noted in the previous office action at paragraph 8). Examiner maintains that future inclusion of the limitation at lines 8-13 with regard to "a bifurcated stent" in combination with "perpendicular hoop members" would raise the issue of new matter. The specification describe a substantially perpendicular embodiment (i.e figures 1-

4a which include the longitudinal displacement feature and are incapable of being considered ***perpendicular***, and a perpendicular embodiment (figures 22-23).

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20,22-25,27-33,39,41,43-49,54-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. Claims 20,22-25,27-33,39,41,43-49,54-57 are rejected because independent claims 54 and 56 recite vertices that abut which is not disclosed in the specification. The specification only discloses juxtaposed vertices. Juxtapose is defined by Merriam Webster's Collegiate Dictionary, 10<sup>th</sup> Ed. as: to place side by side and synonymous with "adjacent". Adjacent is described as: may or may not imply contact but always implies absence of anything of the same kind in between. Furthermore, the attachment mechanisms at page 10 lines 16-23 do not imply the apices must abut (as a weld or adhesive means would imply).

6. Claims 20,22-25,27-33,39,41,43-49,54-55 are rejected because independent claim 54 recites “non-helical” in combination with each hoop being substantially perpendicular and having connected apices. The specification only disclose embodiments wherein each hoop is substantially perpendicular and has connected apices and has a helical “offset” feature.
7. Claims 56-57 recite “the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member” in combination with axially abutting vertices of adjacent hoops, which is not disclosed in the specification. The specification do provide support for the phrase “substantially perpendicular” for the combination, and “perpendicular” for the straight stents of figures 22-23, but the “perpendicular” embodiment is only for “one or more” rather than each or all hoops. This is also supported by original claim 18, the description of figures 1-4, and the amended abstract of 3-1-02.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/  
Primary Examiner  
Art Unit 3774

